K041670

JUL - 6 2004

Appendix D

510(k) Summary

Date: May 28, 2004

Aspect Medical Systems, Inc., 141 Needham St., Newton, MA 02464
Contact Person: Renee Gould (617) 559-7788

Proprietary Name: BIS Pediatric Sensor
Common Name: Electrode, Cutaneous Electrode
Classification: Class II device. Refer to 21 CFR 882.1320

Predicate Devices: K001980, Aspect Pediatric EEG BIS Sensor cleared September 27, 2000 and K002734, Aspect Enhanced XP BIS Sensor cleared September 14, 2000.

Device Description: The Sensor is a single patient use, disposable, pre-gelled 4 electrode array that is applied directly to the pediatric patient's forehead to record electrophysiological signals. It has an electronic smart card memory device in the tab area that contains configuration and identification information.

Indications for Use: The BIS Pediatric Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals in pediatric patients.

Similarities:

- same indications for use as the Pediatric Sensor,
- same intended use as both predicate devices
- same operating principle as both predicate devices: The flexible tines disk, surrounded by the hydrogel, is used to part the outermost layer of skin. While the flexible tines part the skin, hydrogel flows around the tines, forming a conductive bridge with the skin.
- incorporate the same basic design as Enhanced Sensor and same montage,
- incorporate the same materials as both predicate devices,
- have the same shelf life as both predicate devices, and
- is packaged using the same materials and processes as both predicate devices.

Differences:

- smaller size (overall length shorter) and different basepad shape from the Enhanced Sensor to accommodate smaller heads. The "1-2-4-3 basepad "circles" as stated in the Instructions are a different shape. Refer to the Photographs in Section 3. The electrodes have not changed. The shape was changed for better fit.
- addition of the 4th electrode and shape change for better fit to the Pediatric Sensor.

K041670

In summary, the BIS Pediatric Sensor described in this submission is substantially equivalent to the predicate devices. Aspect Medical Systems believes these modifications do not raise new questions of safety or effectiveness. The intended use is the same as both predicate devices. The indications for use remain the same as the Pediatric Sensor. The fundamental scientific technology remains the same as the Pediatric Sensor and Enhanced Sensor predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2004

Aspect Medical Systems, Inc.
c/o Mr. Ned E. Devine, Jr.
Entela, Inc.
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K041670
Trade/Device Name: BIS Pediatric Sensor
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: June 18, 2004
Received: June 21, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix B

Indications for Use Statement

510(k) Number (if known)	K041670
Device Name	BIS Pediatric Sensor
Indications For Use	The BIS Pediatric Sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals in pediatric patients.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041670

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The_Counter Use ____ (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)